Complete Summary

GUIDELINE TITLE

HIV testing and diagnosis in infants and children.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV testing and diagnosis in infants and children. New York (NY): New York State Department of Health; 2005 Feb. 13 p. [14 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Screening

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases

Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Hospitals
Managed Care Organizations
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide guidelines for human immunodeficiency virus (HIV) testing and diagnosis in infants and children

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected infants, children, and adolescents

INTERVENTIONS AND PRACTICES CONSIDERED

1. Laboratory tests for children younger than 18 months of age
    - Human immunodeficiency virus (HIV) deoxyribonucleic acid (DNA) polymerase chain reaction (PCR) at birth, 2 weeks, 4 to 6 weeks, 6 to 12 weeks, and 4 to 6 months of age
    - HIV culture
2. Laboratory tests for children older than 18 months of age
    - Enzyme-linked immunosorbent assay (ELISA)
    - Western blot test for confirmation
3. Rapid test assays
    - OraQuick ADVANCE
    - Reveal Rapid HIV-1 Antibody test
    - Uni-Gold Recombigen HIV Test
4. HIV counseling
    - Pre-test counseling
    - Obtaining consent
    - Post-test counseling
5. HIV reporting and partner notification
6. HIV testing of older children and adolescents with the capacity to consent
7. HIV testing of children in foster care

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3 to 4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one

member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Responsibilities of Child Healthcare Providers

As part of the initial newborn evaluation, the pediatric clinician should determine whether human immunodeficiency virus (HIV) testing of the mother has been completed properly and should follow up on any outstanding laboratory values.

Pediatric clinicians should obtain testing for HIV beyond the neonatal period if the child presents with signs and symptoms of HIV disease. Testing should be performed in children who have not yet been tested when risk factors for HIV infection exist in the child or one of his/her parents.

Laboratory Tests for HIV in Newborns, Children, and Adolescents

Because positive antibody results alone do not establish infection in children younger than 18 months of age, assays to detect virus (HIV deoxyribonucleic acid [DNA] polymerase chain reaction [PCR] or viral culture) should be used for diagnosis (see Figure 1 in the original guideline document).

In children older than 18 months of age, HIV infection may be diagnosed on the basis of a positive HIV antibody test (enzyme-linked immunosorbent assay [ELISA]) and a confirmatory test, such as Western blot.

Because of the time period between infection and the development of detectable antibodies, children/adolescents exposed via sexual activity, sexual abuse/assault, or infected blood who have an initial negative test result should be retested at 1 month, 3 months, and 6 months after exposure.

Because a child with end-stage HIV disease may become HIV-antibody seronegative as a result of severe humoral immunodeficiency, children who are clinically suspected to be HIV-infected yet test HIV antibody negative should be tested by DNA PCR (or HIV culture).

Children older than 18 months of age with an indeterminate Western blot result should be retested as soon as possible. If the Western blot result remains indeterminate, the patient should be tested for HIV-2 or specific viral tests (e.g., DNA PCR) for HIV-1 should be performed.

Rapid testing and expedited preliminary test results prior to Western blot confirmation should generally be used only when immediate information is needed to determine the need for post-exposure prophylaxis in the labor/delivery, newborn, or other acute exposure settings, or when the person who is being tested is unlikely to return for a follow-up visit.

When preliminary diagnostic tests are used for expedited HIV testing, a preliminary positive test result must be confirmed with a Western blot as soon as possible.

Testing for HIV Antibody

See the original guideline document for discussions of screening tests, confirmatory testing of positive results, and rapid test assays.

Testing for HIV or Viral Components

Clinicians should test children younger than 18 months of age who are born to an HIV-infected mother for HIV using one of the following methods:

- HIV DNA PCR (preferred method)
- HIV culture (acceptable method)

Because infection can only be confirmed with two positive test results performed on samples collected at different times, a repeat sample should be obtained promptly for any child with a single positive test result.

In an infant younger than 18 months of age, HIV can be reasonably excluded with two negative HIV viral tests, one at 1 month of age or older, and the other at age 4 months or older.

Ideally, a DNA PCR should be obtained for HIV-exposed infants at each of the following time points:

- at birth
- at 2 weeks of age
- at 4 to 6 weeks of age
- at 6 to 12 weeks of age
- at 4 to 6 months of age

See the original guideline for discussions of HIV DNA PCR, HIV culture, plasma HIV RNA, and HIV antigen detection.

HIV Counseling and Testing

In New York State, written informed consent from the child's biological parent or legal guardian must be obtained before HIV testing can be performed in children except in certain specific circumstances, such as expedited testing, newborn screening, and follow-up PCR testing, and when testing is urgently necessary to provide medical care for a life-threatening condition.

When HIV testing of a child is performed, the parents should be considered for testing as well.

If a child is found to be perinatally HIV infected, his/her siblings also should be tested.

If HIV infection is newly diagnosed in a woman, all of her children should be strongly considered for testing, even if they are asymptomatic.

Pre-Test Counseling

The clinician should counsel the child's parent or guardian or the child/adolescent with capacity to consent prior to HIV testing (see Table 2 in the original guideline document).

In New York State, a minor's right to consent for or refuse HIV testing is based on his/her capacity to understand, without regard to chronological age, what an HIV antibody test actually tests for, the implications/consequences of being HIV infected, and why he/she is at risk for HIV.

The clinician should arrange for follow-up visits at the time of testing and should note in the patient's medical record that counseling was provided and written consent was obtained when required.

When rapid testing is obtained and will yield a preliminary result during the visit, the clinician should first ensure that the patient/parent is emotionally able to receive a positive result and that mental health services are available for patients receiving a positive result.

Obtaining Consent

See the original guideline document for a discussion New York State laws on obtaining consent for HIV testing in children and adolescents for HIV testing.

Post-test Counseling

Counseling after a Patient Receives a Positive Test Result

Positive HIV test results should be presented in person to the appropriate individual (patient, parent, or guardian). A clinician should not communicate results to a patient or family member by telephone or mail.

Clinicians must respect an adolescent's right to confidentiality concerning HIV status.

The clinician should explain the test results and should provide general information about available treatment.

The clinician should discuss the implications of the HIV Reporting/Partner Notification law (refer to the section "HIV Reporting and Partner Notification" below).

The clinician should provide or arrange for necessary referrals for treatment and supportive services.

The clinician should discuss methods of risk reduction and advise the family to inform medical personnel of the child's HIV status during any medical care visit.

Counseling After the Patient Receives a Negative Test Result

When telling a patient that his/her test result is negative, the clinician should educate the patient on how to reduce the risk of transmission in the future.

HIV Reporting and Partner Notification

Since June 2000, New York State has required HIV reporting and partner notification for all confirmed positive HIV tests (unless testing occurred at an anonymous site) and HIV-related tests (available at http://www.health.state.ny.us/nysdoh/hivaids/hivpartner/intro.htm).

During pre-test counseling, parents/children should be informed that if their HIV test result is positive, their names will be reported to the New York State Department of Health.

Parents/children should be informed during pre-test counseling that if they provide the names of sexual or needle-sharing partners, the provider is required to report these names to the State Health Department. They should also be informed that if the test results are positive, their partners will be notified that they have been exposed to HIV.

All sexually active HIV-infected adolescents should be informed about the importance and benefits of notifying partners of their possible exposure to HIV.

Adolescents who are undergoing HIV testing should be questioned regarding the potential for domestic violence if their partners were notified. If domestic violence is a concern, partner notification should be deferred until the risk of harm to the patient (or one close to the patient, e.g., child) is eliminated.

HIV Testing of Older Children and Adolescents With the Capacity to Consent

Clinicians should be knowledgeable about New York State laws pertaining to adolescent consent and confidentiality and should educate their patients about these laws (see the National Guideline Clearinghouse (NGC) summary of the New State Department of Health guideline Identification and Ambulatory Care of HIV-exposed and -infected Adolescents).

In New York State, older children and adolescents who are judged capable of understanding the informed consent process may give written informed consent for HIV testing.

Parents cannot be informed of their child's HIV test results without the explicit consent of the child or adolescent who is deemed capable of providing consent.

Ideally, HIV testing of older children and adolescents should occur in a comprehensive care setting that provides social support, ancillary services, and ongoing health care.

HIV Testing in Children in Foster Care

Within 5 days of entering the foster care system, all children must be assessed for capacity to consent for HIV testing. If a child is determined not to have capacity to consent, an HIV risk assessment must also be completed within the first 5 days of entering foster care. Children already in foster care must be assessed for HIV risk factors at least 60 days prior to their next scheduled periodic medical examination. If it is determined that a child may have the capacity to consent, an assessment of capacity to consent must be made and documented by authorized foster care agency staff within 30 days of the child's entry into foster care. An HIV risk assessment must also be completed within this timeframe.

If one or more risk factors are present, a child in foster care should be offered HIV testing, or if the child lacks capacity to consent, he/she should be tested for HIV infection.

Adolescents and older children in foster care with the capacity to consent for HIV testing have the right to either consent for their own test or refuse testing.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Determination of Infection Status in HIV Exposed Children <18 Months of Age
- Expedited Maternal-Newborn HIV Testing Using a Rapid, Single Use Device
- Expedited Maternal-Newborn HIV Testing Using Instrumented Methods

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate human immunodeficiency virus (HIV) testing and diagnosis in infants and children
- Identification of HIV infection will allow for provision of optimal antiretroviral prophylaxis and treatment.

POTENTIAL HARMS

Human immunodeficiency virus (HIV) testing may result in false-positive or false-negative results.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening, or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience.
- Define target audience (providers, consumers, support service providers).
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?

    - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
    - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
    - Did the processes and strategies work? Were the guidelines implemented?
    - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV testing and diagnosis in infants and children. New York (NY): New York State Department of Health; 2005 Feb. 13 p. [14 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Feb

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Committee for the Care of Children and Adolescents with HIV Infection.

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Jeffrey M. Birnbaum, MD, MPH (Chair) Assistant Professor of Pediatrics, SUNY Health Sciences Center at Downstate, Brooklyn, New York, Director, HEAT Program, Kings County Hospital; Geoffrey A. Weinberg, MD (Vice Chair) Director, Pediatric HIV Program, Strong Memorial Hospital, Rochester, NY, Associate Professor of Pediatrics, Division of Infectious Diseases, University of Rochester School of Medicine and Dentistry; Jacobo Abadi, MD, Assistant Professor of Pediatrics, Albert Einstein College of Medicine, Bronx, New York, Jacobi Medical Center; Saroj S. Bakshi, MD, Associate Professor of Clinical Pediatrics, Albert Einstein College of Medicine, Bronx, New York, Chief, Division of Pediatric Infectious Diseases, Bronx-Lebanon Hospital Center; Howard J. Balbi, MD, Associate Professor of Pediatrics, SUNY at Stony Brook School of Medicine, Director, Pediatric Infectious Diseases, Good Samaritan Hospital Medical Center; Joseph S. Cervia, MD, Associate Professor of Clinical Medicine and Pediatrics, Albert Einstein College of Medicine, Bronx, New York, Director, The Comprehensive HIV Care and Research Center, Long Island Jewish Medical Center; Aracelis D. Fernandez, MD, Assistant Professor of Pediatrics, Albany Medical College; Ed Handelsman, MD, Assistant Professor of Pediatrics, SUNY Health Sciences Center at Downstate, Assistant Medical Director of Pediatrics, Office of the Medical Director, AIDS Institute; Sharon Nachman, MD, Chief, Pediatric Infectious Diseases, Professor of Pediatrics, SUNY at Stony Brook; Natalie Neu, MD, Assistant Professor of Pediatrics, Division of Pediatric Infectious Diseases, Columbia University; Catherine J. Painter, MD, PhD, Assistant Professor of Clinical Pediatrics, College of Physicians and Surgeons, Columbia University, New York, New York, Medical Director, Incarnation Children's Center; Roberto Posada, MD, Assistant Professor of Pediatrics, Division of Pediatric Infectious Diseases, Mount Sinai School of Medicine, New York, New York, Director, Pediatric HIV Program, Mount Sinai Hospital; Michael G. Rosenberg, MD, PhD, Associate Professor of Clinical Pediatrics, Albert Einstein College of Medicine, Bronx, New York, Pediatric Consultation Services, Jacobi Medical Center; Pauline Thomas, MD, Assistant Professor, Dept. of OB/GYN and Women's Health, Dept. of Preventive Medicine and Community Health, New Jersey Medical School; Barbara Warren, BSN, MPH, PNP, Assistant Director, Bureau of HIV Ambulatory Care Services, AIDS Institute, New York State Department of Health

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p.

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

PATIENT RESOURCES

None available

NGC STATUS

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Date Modified: 10/2/2006